

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re U.S. Patent No.: 7,052,679  
Inventors: Joshua D. Rabinowitz et al.  
Issue Date: May 30, 2006  
For: DELIVERY OF ANTIPSYCHOTICS  
THROUGH AN INHALATION  
ROUTE

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

**REQUEST FOR CERTIFICATE OF CORRECTION**

Pursuant to 35 U.S.C. § 255 and 37 C.F.R. § 1.323, this is a request for the issuance of a Certificate of Correction in the above-identified patent. Two (2) copies of PTO Form 1050 are appended. The complete Certificate of Correction involves one (1) page.

The mistake identified in the attached Form concerns the systematic (IUPAC) name for the drug loxapine which appears at column 12, lines 3-4 of the patent. The name reads:

2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine.

The name should read:

2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine.

The systematic name for loxapine is well-documented, e.g., in scientifically accepted references such as The Merck Index. See, The Merck Index – An Encyclopedia of Chemicals, Drugs and Biologicals, 13th Ed., Maryadele J. O'Neil et al. (Eds.). Merck & Co., Inc. Whitehouse Station, NJ, 2001, p. 1001 (#5609) (attached).

The mistake identified in the attached Form is of a clerical or typographical nature, or of a minor character, and resulted from an error made in good faith by applicants. Therefore, Issuance of a Certificate of Correction correcting this error is requested.

The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to Deposit Account No. 19-5117.

Respectfully submitted,

Date: April 17, 2008

/Katherine Lobel-Rice/

Katherine Lobel-Rice, #58,079  
Swanson & Bratschun, L.L.C.  
8210 SouthPark Terrace  
Littleton, Colorado 80120  
Telephone: (303) 268-0066  
Facsimile: (303) 268-0065

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CERTIFICATE OF CORRECTIONPage 1 of 1

PATENT NO. : 7,052,679 B2

APPLICATION NO.: 10/767,115

ISSUE DATE : May 30, 2006

INVENTOR(S) : Joshua D. Rabinowitz et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, lines 3-4, "2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]diazepine" should read  
--2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine--.

## MAILING ADDRESS OF SENDER (Please do not use customer number below):

Swanson & Bratschun, LLC  
8210 SouthPark Terrace  
Littleton, CO 80120

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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# THE MERCK INDEX

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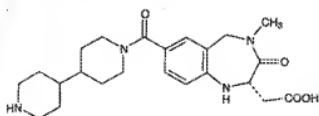
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to Du Pont); D-11. Angiotensin II receptor antagonists: A. T. Chilko et al., *J. Am. Med. Inf. Assoc.* 2, 1195 (1990); P. C. Wong et al., *Proc. 1991 Int. Symposium on Drugs and Disease: McIntyre et al., Effect on mortality* 5, 1582 (2000); 5-6.

Pont 753; DUP-60-Lotan; Oscar; ochlorothiazide.

228 (1998). Clinical evaluation in patients with coronary or cerebral atherosclerosis: R. A. Harrington et al., *Circulation* 102, 728 (2000).

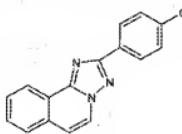


Zwitterionic.  $[\alpha]_D^{20} = -201^\circ$  ( $c = 0.5$  in methanol).  
THERAP CAT: Antithrombotic.

**5607. Lotrifén.** [66535-86-2] 2-(4-Chlorophenyl)-1,2,4-triazolo[5,1-a]isoquinoline-1,3-dione.  $[\alpha]_D^{20} = +323^\circ$  ( $c = 0.5$  in 100 ml acetonitrile). uv max: 231, 238, 247 nm ( $\lambda_1^{1\%}$  532, 621, 418). Solv at room temp (mg/ml): acetone 47, acetonitrile 28, *n*-butanol 7, *t*-butanol 14, chloroform 350, *N,N*-dimethylformamide 90, ethanol 16, methanol 28, *n*-octanol 2, *n*-propanol 11, *t*-propanol 20, water  $0.4 \times 10^3$ . LD<sub>50</sub> orally in mice: >1000 mg/kg (Endo).

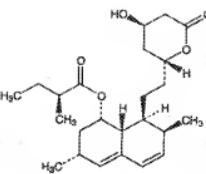
THERAP CAT: Antithrombotic.

**5609. Loxapine.** [1977-10-2] 2-Chloro-11-(4-methyl-1-piperazinyl) dibenz[b,f] [1,4]oxazepine; oxapiline; CL-62362; S-805; SUM-3170. C<sub>18</sub>H<sub>21</sub>ClN<sub>3</sub>O; mol wt 327.82. C 65.95%, H 5.53%, Cl 10.81%, N 12.82%; O 4.88%. Prepn: NL 6406089 correspond to Schmutz et al., US 3546226 (1964, 1970 both to Wander); *eidem* *Helv. Chim. Acta* 50, 245 (1967); Coppola, US 3412193 (1968 to Am. Cyanamid). Crystal structure: D. B. Cosulich, F. M. Lovell, *Acta Crystallogr.* 33B, 1147 (1977). Pharmacology: Schmutz et al., *Chem. Ther.* 2, 424 (1967); Latimer, *Pharmacol. Exp. Ther.* 166, 151 (1969). Toxicity data: Stille et al., *Arzneimittel-Forsch.* 15, 841 (1965). Toxicity studies: Minoshita et al., *Oyo Yakuri* 4, 293 (1970). C. D. 76, 81145v (1972). Review of pharmacology and therapeutic efficacy: R. C. Heel et al., *Drugs* 15, 198-217 (1978).



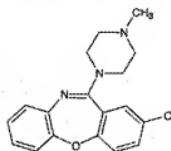
Crystals mp 238-240°.  
THERAP CAT (VET): Abortifacient.

**5608. Lovastatin.** [7530-75-5] (2S)-2-Methylbutanoic acid (1S,3R,7S,8aR)-1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-(2R,4R)-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl]ethyl-1-naphthalenyl ester. (1S,3R,7S,8S,8aR)-1,2,3,7,8a-hexahydro-3,7-dimethyl-8-[2-(2R,4R)-tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl]ethyl-1-naphthalenyl (3S)-2-methylbutyrate; 1,2,6,7,8,8a-hexahydro- $\beta$ , $\beta$ -dihydroxy-2,6-dimethyl-8-(2-methyl-1-oxobutoxy)-1-naphthalenepheptanoic acid 8-lactone; 2,6,6a-dimethyl-8-(2-methyl-1-oxobutoxy)mevinic acid lactone; mevinolin; 6a-methylcompactin; monacolin K; MK-803; Lovalip; Mevorac; Mevinacor; Mevlor; Sivlor. C<sub>28</sub>H<sub>38</sub>O<sub>4</sub>; mol wt 404.54. C 71.26%, H 8.97%, O 19.77%. Fungal metabolite; potent inhibitor of HMG-CoA reductase, the rate controlling enzyme in cholesterol biosynthesis. Isolated from *Monascus ruber*: A. Endo, *J. Antibiot.* 32, 852 (1979); from *Aspergillus terreus*: R. L. Monaghan et al., US 4219338 (1980 to Merck & Co.). Structure and biochemical properties: A. W. Alberts et al., *Proc. Natl. Acad. Sci. USA* 77, 3957 (1980). Total synthesis: M. Hirama, M. Iwashita, *Tetrahedron Letters* 24, 181 (1983). Review of syntheses: T. Rosen, C. H. Heathcock, *Tetrahedron* 42, 4909-4951 (1986). Biosynthesis: M. D. Greenspan, J. B. Yudkowitz, *J. Bacteriol.* 162, 704 (1985); R. N. Moore et al., *J. Am. Chem. Soc.* 107, 3694 (1985). HPLC detection in plasma and bile: R. J. Stubbs et al., *J. Chromatog.* 383, 438 (1986). Clinical pharmacology: S. M. Grundy, G. L. Vega, *J. Lipid Res.* 26, 1464 (1985). Clinical comparison with gemfibrozil, q.v.: M. J. Tikkainen et al., *Am. J. Cardiol.* 62, 353 (1988). Review of clinical experience: J. A. Tober, *Am. J. Cardiol.* 62, 281-341 (1988). Comprehensive description: G. S. Brenner et al., *Anal. Profiles Drug Subs. Escip.* 21, 277-305 (1992). Prevention of acute coronary events in men and women with average cholesterol levels: J. R. Downs et al., *J. Am. Med. Assoc.* 279, 1615 (1998).



White crystals, mp (under N<sub>2</sub>): 174.5°.  $[\alpha]_D^{20} = +323^\circ$  ( $c = 0.5$  in 100 ml acetonitrile). uv max: 231, 238, 247 nm ( $\lambda_1^{1\%}$  532, 621, 418). Solv at room temp (mg/ml): acetone 47, acetonitrile 28, *n*-butanol 7, *t*-butanol 14, chloroform 350, *N,N*-dimethylformamide 90, ethanol 16, methanol 28, *n*-octanol 2, *n*-propanol 11, *t*-propanol 20, water  $0.4 \times 10^3$ . LD<sub>50</sub> orally in mice: >1000 mg/kg (Endo).

THERAP CAT: Antithrombotic.



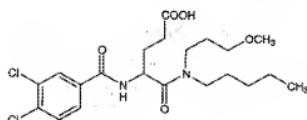
Pale yellowish crystals from petr ether, mp 109-110°. LD<sub>50</sub> orally in mice: 65 mg/kg (Stille).

**Hydrochloride.** Loxitane. C<sub>18</sub>H<sub>15</sub>ClN<sub>3</sub>O.HCl; mol wt 364.28.

**Succinate.** [27833-64-3] CL-71563; Loxapac; Loxitane. C<sub>18</sub>H<sub>15</sub>ClN<sub>3</sub>O<sub>4</sub>C<sub>4</sub>H<sub>6</sub>O<sub>4</sub>; mol wt 445.90.

THERAP CAT: Anxiolytic.

**5610. Loxiglumide.** [107097-80-3] 4-[(3,4-Dichlorobenzyl)amino]-5-(3-methoxypropyl)pentylamino]-5-oxopentanoic acid; (±)-4-(3,4-dichlorobenzamido)-N-(3-methoxypropyl)-N-pentylglutaramic acid; CR-1505. C<sub>21</sub>H<sub>23</sub>Cl<sub>2</sub>N<sub>3</sub>O<sub>5</sub>; mol wt 461.39. C 54.67%, H 6.55%, Cl 15.37%, N 6.07%, O 17.34%. Cholecytokinin A (CCK-A) antagonist. Prepn: F. Makovec et al., WO 87 03869; *eidem*, US 4769389 (1987, 1988 both to Rotta). Pharmacology and receptor binding: I. Setnikar et al., *Arzneimittel-Forsch.* 37, 703 (1987). Pharmacokinetics:



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--2-chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f]-[1,4]oxazepine--.

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